

### Applicants' Statement of the Substance of Interview

A personal interview was held on June 6, 2006 in connection with this application. Participants were Supervisory Examiner Ardin Marschel, Examiners Frederick Krass and Lezah Roberts, and Messrs. Richard Girards and Hoon Choi, attorneys for Applicants. Applicants wish to thank Examiners Marschel, Krass and Roberts for the courtesy they extended to attorneys for Applicants during the interview.

First, the rejection under 35 U.S.C. §132(a), *i.e.*, the new matter rejection, was discussed. Attorneys for Applicants first pointed out that the term "direct-blend" is adequately described in the specification, and thus, is not new matter. In particular, Attorneys for Applicants pointed to Section 4.2 of the specification, wherein a process for manufacturing a "direct-blend" composition is disclosed in sections 4.2.1, 4.2.2, 4.2.4 and 4.2.5. The Examiners were of the opinion that, despite the disclosures in that portion of the specification, it is still unclear what the term "direct-blend" means. The Examiners then suggested, based on page 12, lines 26-29 of the specification, that amending the claims to recite "a uniform admixture" would be favorably considered. Attorneys for Applicants stated that Applicants would consider making such an amendment.

With regard to the rejections under 35 U.S.C. §103, Attorneys for Applicants presented the Examiners with proposed claim amendments wherein the term "carrier" recited by the claims was replaced with "pregelatinized corn starch." The Examiners agreed that such amendments would adequately address the current rejections, but required that Applicants submit evidence that the term "pregelatinized corn starch" has a scope that can be readily defined and understood by those skilled in the art. Attorneys for Applicants agreed to file such evidence in the response.

Finally, the prior art references of record were discussed. Attorneys for Applicants stated that the claims should be patentable in view of the fact that, while the cited prior art references may disclose the ingredients of the claimed composition in general and broad terms, none of the references disclose the specific amounts of each of the ingredients in the specific capsule sizes as recited by the claims. In addition, Attorneys for Applicants pointed out that the surprising bioequivalence of the claimed compositions and the formulation commercially available at the time of this invention were submitted in the previous response. Attorneys for Applicants also pointed out that the commercially available composition, due to its large size, presented problems with regard to convenience and patient compliance.

The Examiners agreed that, subject to their verification of what was submitted in the previous response, the claims appear to be distinguished from the prior art

disclosures. The Examiners also agreed that the secondary considerations for assessing obviousness also weigh in favor of the nonobviousness of the claimed invention, due, in part, to the fact that long-felt need has been satisfied by the claimed invention.